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TO:

Name: Mail Stop AMENDMENT
Group Art Unit 3764/Examiner Michael Brown

Firm: U.S. Patent & Trademark Office

Fax No.: 571-273-4702

Subject: U.S. Patent Application No. 08/480,908
Gary K. Michelson
Filed: June 7, 1995
THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS
Attorney Docket No. 101.0053-00000
Customer No. 22882

FROM:

Name: Thomas H. Martin, Esq.

Phone No.: 330-877-2277

No. of Pages (including this): 55

Date: September 30, 2005

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TRANSMISSION 2 OF 4

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Todd M. Martin

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EXHIBIT A

Letters Patent Application by Gary Karlin Michelson, M.D.

for Improved Partially Conical Interbody Spinal Fusion Implants.

Background

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space (the space between adjacent vertebrae normally occupied by a spinal disc). Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared space spanning the disc and penetrating into each of the adjacent vertebrae, which space may be produced by use of a drill. It is an anatomical fact that both the cervical and the lumbar spine are normally lordotic (convex forward); and that such alignment is important to the proper functioning of those areas. However, not uncommonly, the very conditions which require treatment by spinal fusion are associated with a loss of lordosis. Michelson in _____, teaches a method for restoring the lordosis while performing the interbody fusion procedure.

[REDACTED]

The present invention consists of a variety of interbody spinal implants, all having in common that they are at least partially conical and the instrumentation and methods by which these implants can be utilized to achieve the desired lumbar lordosis while performing spinal interbody fusion.

The present invention artificial spinal implants can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, these implants may be comprised wholly or in part of materials capable of directly participating in the fusion process, or coated with chemical substances such as bone morphogenic proteins for the purpose of stimulating fusion activity. These implants may be partially or fully conical, but having truncated ends. Said implants may be further modified so that while the upper and lower surfaces are portions of a cone, the side portions form straight walls. These implants may have a more tapered aspect at the small end of the cone. Further, these structures may be relatively solid, may have surface roughenings to promote bone ingrowth, surface roughenings to promote stability, may have wells extending into the substance from the

EXHIBIT B

APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR IMPROVED PARTIALLY CONICAL INTERBODY SPINAL FUSION IMPLANTS

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Signed: _____

Typed or Printed Name Roxanne Becker

Date: [REDACTED]

BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference. This application is also a continuation in part of copending United States application Serial No. 08/219,626 filed on March 28, 1994 which is incorporated herein by reference.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space (the space between adjacent vertebrae normally occupied by a spinal disc). Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared space spanning the disc and penetrating into each of the adjacent vertebrae, which space may be produced by use of a drill. It is an anatomical fact that both the cervical and the lumbar spine are normally lordotic (convex forward); and that such alignment is important to the proper functioning of those areas. However, not uncommonly, the very conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson in U.S. Patent Application Serial No. _____, teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion

procedure. [REDACTED]

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal implants, all having in common that they are at least partially conical; and is directed to the instrumentation and methods by which the implants of the present invention can be utilized to achieve the desired anatomical lordosis while performing spinal interbody fusion.

The spinal fusion implants of the present invention may be partially or fully conical, but having truncated ends. Said implants may be further modified so that while the upper and lower surfaces are portions of a cone, the side portions form straight walls. These implants may have a more tapered aspect at the small end of the cone. Further, these structures may be relatively solid, may have surface roughenings to promote bone ingrowth, surface roughenings to promote stability, may have wells extending into the substance from the surface for the purpose of holding fusion promoting materials, may have holes passing either into or through the implant, may have a hollow central chamber, which chamber may be a communication through various openings to the surface of the implant and which chamber may be capable of being closed off with a cap. Still further, a variety of surface irregularities may be employed for further purposes of increasing stability, increasing surface area, and/or for the purpose of advancing the implant into the fusion site. For those purposes, the exterior of the implant may, wholly or in part, be rough-blast finished, have knurling, concentric rings. forward facing ratchetings or thread. The implants may be made of a mesh-like material.

The spinal fusion implants of the present invention offer significant advantages over prior implants spinal fusion implants:

1. Because the implants are at least partially conical and taper from the leading edge to the trailing edge, they are easy to introduce and easy to fully insert into the spinal segment to be fused.

2. As the spinal fusion implants of the present invention are generally implanted from the anterior to posterior aspect in the spine, the shape of the implants are consistent with the shape of the disc, which the implant at least in part replaces, in that the front of the disc is normally taller than the back of the disc, which allows for normal lordosis, and the present invention implants are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention implant allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody fusion in lordosis.

4. The spinal fusion implants of the present implant conform to a geometric shape, which shape is readily producible at the site of fusion to receive the spinal fusion implant.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, these implants may be comprised wholly or in part of materials capable of directly participating in the fusion process, or coated with chemical substances such as bone morphogenic proteins for the purpose of stimulating fusion activity.

OBJECTS OF THE PRESENT INVENTION

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is partially conical and an even cylindrical external thread.

Figure 2 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body and an external thread that are partially conical.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having a partially conical body and a surface configuration comprising ratchetings for engaging bone, with surface blasting, wells and channels for bone ingrowth.

Figure 5 is a cross sectional along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the implant of the present invention.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous metal mesh and is partially conical with one truncated side.

Figure 7 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is partially conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 8 is an enlarged view along line 8 of Figure 7 illustrating the surface configuration of the implant of Figure 7.

DETAILED DESCRIPTION OF THE DRAWINGS

[REDACTED]

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body ## that is partially conical in shape and has external threads # that form an even cylindrical external thread, such that the diameter of the body # (root diameter) is partially conical while the external diameter of the threads (major diameter) has an even cylindrical configuration. The configuration of the implant 20 allows the for the creating and maintaining of the adjacent vertebrae of the spine in an angular relationship to each other in order to preserve or restore the anatomic lordosis of the spine. The external threads # are configured in a substantially cylindrical shape in order to engage the bone in a position that counters the forces which tend to urge the implant 20 out from between the adjacent vertebrae in the direction in which it was implanted.

Referring to Figure 2, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 120. The implant 120 has a body # that is partial conical and an external thread # that parallels the body # such that the external threads are also partially conical.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has a thin outer wall 112 surrounding an internal chamber 114 and a longitudinal central axis L. The wall 112 has openings 128 passing therethrough to communicate with the internal chamber 114. The internal chamber 114 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae V through the openings 128 to the material within internal chamber 114. While the openings 128 have been shown in the drawings as being circular, it is appreciated that the openings 128 may have any shape, size, or form suitable

for use in a spinal fusion implant without departing from the scope of the present invention. Also, the number of openings may be varied or no openings may be present on the spinal fusion implant.

The implant 120 has a cap 130 with a thread 132 that threadably attaches to one end of the spinal fusion implant 100. The cap 130 is removable to provide access to the internal chamber 114, such that the internal chamber 114 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 130 and/or the spinal fusion implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral #. The implant # has a partially conical body # and a surface configuration comprising ratchetings for engaging bone, with surface blasting, wells and channels for bone ingrowth.

Referring to Figure 5, a cross sectional along line 5--5 of implant # is shown illustrating the channels # passing through the implant # and wells # in the surface of the implant #.

Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral #. The implant # has a body # that is made out of a fibrous metal mesh. The mesh # comprises a matrix of fibrous metal strands having spaces # between the metal strands allowing for bone ingrowth.

The implant # is partially conical and has at least one truncated side allowing the placement of two implants # closer together when placed side by side between two adjacent vertebrae as

set forth in U.S. Patent Application Serial No. _____ incorporated herein by reference.

Referring to Figure 7, a side elevational view of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral #. The implant # has a body # that is partially conical in shape. The implant # has a surface configuration comprising a plurality of posts # that are spaced apart to provide a plurality of interstices capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. Bone growth is promoted into the interstices # such that a bone mass incorporating the implant # is formed during fusion to permanently fix areas to permit bone ingrowth.

Referring to Figure 8, an enlarged view of the surface configuration of implant #. In the preferred embodiment, the posts # have a head of larger diameter that the remainder of the posts # and the each of the interstices # is the reverse configuration of the posts # having a bottom # that is wider than the entrance # to the bottom #. Such a configuration of the posts # and interstices # aids in the retention of bone material in the surface of the implant # and further assists in the locking of the implant # into the bone fusion mass created from the bone ingrowth.

The embodiments of the implants of the present invention described above may be implanted with the method described below.

Description of the method for the cervical spine:

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of

distraction and lordosis has been achieved at the affected level, then a conical space is created from anterior to posterior between the adjacent vertebrae, such space is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae and which space is generally conical, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepared two such spaces side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the space is prepared and all debris removed, the implant is then inserted into the space across the disc space, penetrating into each of the adjacent vertebrae.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. [REDACTED] _____ is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the cervical spine. As previously described in pending U.S. Patent Application Serial No. _____, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. _____, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described interspace distractor. However, if the interspace distractor is

used thereafter the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

In the preferred embodiment, the implant itself is a threaded cone and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root diameter of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion corresponding to the conical shape of the root diameter of the implant. This instrument may take the form of a conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with a power. At this time, the surgeon has two options. One is to remove the outer sleeve and then, because the implant is itself conical, screw the implant in using an implant driver capable of locking to the implant. The insertion of the implant causes a reproduction of the previous distraction which is easily achieved as the implant itself is conical and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the device is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from it. If the cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same levels that a pair of such implants may be inserted side-by-side.

However, if the surgeon wishes to leave the outer sleeve

in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the drilling means needs to basically correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be groat enough to allow the passage of the major diameter of the implant. Nevertheless, it is desirable to stabilize the previously described bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. That is achieved in one of two ways. First, a reduction sleeve may be introduced, which sleeve fit between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant, or secondary, some portion of the drill shaft proximal to the actual part engaged in the removal of bone may have a diameter which roughly corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In that way, the bone removal instrument is both stabilized and centered within the outer sleeve. The basic described principles of the prior discussion are also applicable to the lumbar spine. The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No._____

[REDACTED]

As also previously described, in that co-pending application _____, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application _____, the implants themselves may have tangential

truncations such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height.

In the alternative, the use of the at least partially conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is present to begin with. As an example, a disc space which in the preferred circumstance would be fully distracted but need not be, could have a bore drilled across that space such that equal arcs of bone are removed from each of the adjacent vertebrae using a drill or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The essential feature here is that the vertebrae, whether distracted from each other or not are essentially lacking the full restoration of lordosis. The use of the essentially cylindrical bone removal instrument, be it a drill, a mill, or other, provides for the generally uniform removal of bone as regards thickness from anterior to posterior. The insertion of a conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart from each other more so than the posterior aspects where the diameter is lesser. This in essence utilizes the implant to produce lordosis even though no such lordosis is present up until the time of the initial implant insertion.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

What is claimed is:

ABSTRACT

EXHIBIT C

APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR IMPROVED PARTIALLY CONICAL INTERBODY SPINAL FUSION IMPLANTS

CERTIFICATE OF EXPRESS MAILING

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PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231.

Signed:

Typed or Printed Name: A Sandra Mireles

Date: [REDACTED]

BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference. This application is also a continuation in part of copending United States application Serial No. 08/219,626 filed on March 28, 1994 which is incorporated herein by reference. **[TITLE: APPARATUS, INSTRUMENTATION AND METHOD FOR SPINAL FIXATION]** This application is also a continuation-in-part of United States application Serial No. _____ [REDACTED] filed on February 17, 1995.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared opening spanning the disc space and penetrating into each of the adjacent vertebrae such an opening may be created by use of a drill. It is an anatomical fact that both the cervical and the lumbar spine are normally lordotic such that the normal angular relationship of the

vertebrae of the spine form a curve that is convex forward; and that such alignment is important to the proper functioning of those areas. However, not uncommonly, the very conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson in U.S. Patent Application Serial No. 08/396,414, entitled APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure.

[REDACTED]

Therefore, there exists a need for spinal fusion implant and instrumentation that permits the even removal of bone from each of the adjacent vertebrae while restoring anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal implants, all having in common that they are at least partially conical and is also directed to the instrumentation and methods by which the implants of the present invention can be utilized to achieve the desired anatomical lordosis while performing spinal interbody fusion.

The spinal fusion implants of the present invention may be partially or fully conical with truncated ends. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a cone, the side portions form straight walls. These implants may have a more tapered aspect at the small end of the cone to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid, may have surface roughenings to promote bone ingrowth, surface roughenings to promote stability, may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials, may have holes passing either into or through the implant, may have a hollow

central chamber, which chamber may be in communication through various openings to the surface of the implant and which chamber may be capable of being closed off with a cap. Still further, a variety of surface irregularities may be employed for further purposes of increasing stability, increasing surface area, and/or for the purpose of advancing the spinal fusion implant of the present invention into the fusion site. For those purposes, the exterior of the spinal fusion implant of the present invention, wholly or in part, may be rough-blast finished, have knurling, concentric rings, forward facing ratchetings or threads. The spinal fusion implant of the present invention may be made of a mesh-like material.

The spinal fusion implants of the present invention offer significant advantages over prior implants spinal fusion implants:

1. Because the spinal fusion implants of the present invention are at least partially conical and taper from the leading edge to the trailing edge, they are easy to introduce and easy to fully insert into the spinal segment to be fused;

2. As the spinal fusion implants of the present invention are generally implanted from the anterior to posterior aspect in the spine, the shape of the implants are consistent with the shape of the disc, which the implant at least in part replaces, in that the front of the disc is normally taller than the back of the disc, which allows for normal lordosis, and the present invention implants are similarly taller anteriorly than they are posteriorly;

3. The spinal fusion implants of the present invention implant allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody fusion in lordosis; and

4. The spinal fusion implants of the present implant conform to a geometric shape, which shape is readily producible at the site of fusion to receive the spinal fusion implant.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, the spinal fusion implants of the present invention may be comprised, wholly or in part, of materials capable of directly participating in the spinal fusion process, or coated with chemical substances such as bone morphogenic proteins for the purpose of stimulating fusion activity.

OBJECTS OF THE PRESENT INVENTION

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is partially conical and an even cylindrical external thread.

Figure 2 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body and an external thread that are partially conical.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having a partially conical body and a surface configuration comprising ratchetings for engaging bone, with surface blasting, wells and channels for bone ingrowth.

Figure 5 is a cross sectional view along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the

implant of the present invention.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous metal mesh and is partially conical with one truncated side.

Figure 7 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is partially conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 8 is an enlarged view along line 8 of Figure 7 illustrating the surface configuration of the implant of Figure 7.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body # that is partially conical in shape such that the body # has a diameter (root diameter) that is partially conical. The implant 20 has external threads # that form an even cylindrical external thread, such that the external diameter of the threads (major diameter) has an even cylindrical configuration. The conical configuration of the body # allows for the creating and maintaining of the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The external threads # of the implant 20 are configured in a substantially cylindrical shape in order to engage the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the opposite direction in which the implant 20 was implanted.

Referring to Figure 2, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 120. The implant 120 has a body # that is partially conical similar to body # of implant 20 and has an external thread # that parallels the body # such that

the external thread # is also partially conical in shape.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has a thin outer wall 112 surrounding an internal chamber 114 and has openings 128 passing therethrough to communicate with the internal chamber 114. The internal chamber 114 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 128 to the material within internal chamber 114. While the openings 128 have been shown in the drawings as being circular, it is appreciated that the openings 128 may have any shape, size, or form suitable for use in a spinal fusion implant without departing from the scope of the present invention. Also, the number of openings may be varied or no openings may be present on the spinal fusion implant.

The implant 120 has a cap 130 with a thread 132 that threadably attaches to one end of the spinal fusion implant 100. The cap 130 is removable to provide access to the internal chamber 114, such that the internal chamber 114 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate, or bone morphogenic protein. The cap 130 and/or the spinal fusion implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a partially conical body # that is similar to body # of implant 20 and has a surface configuration suitable for engaging the bone of the adjacent vertebrae. The surface configuration of the implant

220 may comprise ratchetings for engaging bone, with surface blasting, wells and channels for promoting bone ingrowth.

Referring to Figure 5, a cross sectional view of implant 220 is shown. The implant 220 has channels # passing through the implant 220 and wells # formed in the surface of the implant 220. The wells # may or may not communicate with the channels #. In the preferred embodiment of implant 220, the channels # have a diameter in the range of _____mm to _____mm, with _____mm being the preferred diameter. The wells # have a diameter in the range of ____mm to ____mm with _____mm being the preferred diameter. It is appreciated that although the channels # and wells # are shown having a generally rounded configuration, it is within the scope of the present invention that the channels # and wells # may have any shape and configuration suitable for the intended purpose.

Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320. The implant 320 has a body # that is made out of a fibrous metal strands molded into a conical configuration. The fibrous metal strands formed and pressed together such that are spaces # are present between the fibrous metal strands which allowing for bone ingrowth.

The implant 320 is partially conical, similar to implant 20, and in addition has at least one truncated side allowing the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No. _____ incorporated herein by reference.

Referring to Figure 7, a side elevational view of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body # that is partially conical in shape and has a surface # that is capable of receiving and holding natural or artificial bone material and capable of promoting bone ingrowth. In the preferred embodiment, the surface # comprises a plurality of posts # that are spaced apart to provide a plurality of interstices # capable of holding and retaining milled bone material or any

artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by filling the Moreover, once implanted, bone growth is promoted into the interstices # such that a bone mass incorporating the implant 420 is formed during fusion to permanently fix areas to permit bone ingrowth.

Referring to Figure 8, an enlarged view of the surface # of implant 420 is shown. In the preferred embodiment, the posts # have a head portion # of a larger diameter than the remainder of the posts #, and the each of the interstices # is the reverse configuration of the posts # having a bottom # that is wider than the entrance # to the bottom #. Such a configuration of the posts # and interstices # aids in the retention of bone material in the surface # of the implant # and further assists in the locking of the implant # into the bone fusion mass created from the bone ingrowth.

In the preferred embodiment, the posts # have a maximum diameter of approximately 1mm and a height of approximately 1mm and are spaced apart a distance of approximately 1mm such that the interstices # have a width of approximately 1mm.

The embodiments of the implants of the present invention described above may be implanted with the method described below.

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis has been achieved at the affected disc level, then a conical space is created from anterior to posterior between the adjacent vertebrae. The space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae.

The created space is generally conical in shape , being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepared two such spaces side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the space is prepared and all debris removed, the implant is then inserted into the space across the disc space, penetrating into each of the adjacent vertebrae.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. 08/396,414 incorporated herein by reference is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the cervical spine. As previously described in pending U.S. Patent Application Serial No. _____, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. _____, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described interspace distractor. However, if the interspace distractor is used thereafter the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

In the preferred embodiment, the implant itself is a

threaded cone and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root diameter of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion corresponding to the conical shape of the root diameter of the implant. This instrument may take the form of a conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with a power. At this time, the surgeon has two options: One is to remove the outer sleeve and then, because the implant is itself conical, screw the implant in using an implant driver capable of locking to the implant. The insertion of the implant causes a reproduction of the previous distraction which is easily achieved as the implant itself is conical and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the device is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from it. If the cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same levels that a pair of such implants may be inserted side-by-side.

However, if the surgeon wishes to leave the outer sleeve in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the drilling means needs to basically correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be groat enough to allow the

passage of the major diameter of the implant. Nevertheless, it is desirable to stabilize the previously described bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. That is achieved in one of two ways. First, a reduction sleeve may be introduced, which sleeve fit between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant, or secondary, some portion of the drill shaft proximal to the actual part engaged in the removal of bone may have a diameter which roughly corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In that way, the bone removal instrument is both stabilized and centered within the outer sleeve. The basic described principles of the prior discussion are also applicable to the lumbar spine. The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No._____

[REDACTED]

As also previously described, in that co-pending application _____, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application _____, the implants themselves may have tangential truncations such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height.

In the alternative, the use of the at least partially conical interbody spinal fusion implants allows for the creation of

lordosis by the implant itself where none is present to begin with. As an example, a disc space which in the preferred circumstance would be fully distracted but need not be, could have a bore drilled across that space such that equal arcs of bone are removed from each of the adjacent vertebrae using a drill or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The essential feature here is that the vertebrae, whether distracted from each other or not are essentially lacking the full restoration of lordosis. The use of the essentially cylindrical bone removal instrument, be it a drill, a mill, or other, provides for the generally uniform removal of bone as regards thickness from anterior to posterior. The insertion of a conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart from each other more so than the posterior aspects where the diameter is lesser. This in essence utilizes the implant to produce lordosis even though no such lordosis is present up until the time of the initial implant insertion.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

What is claimed is:

ABSTRACT

EXHIBIT D

APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR

IMPROVED PARTIALLY CONICAL INTERBODY

SPINAL FUSION IMPLANTS

CERTIFICATE OF EXPRESS MAILING

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BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference.

This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae, such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson in U.S. Patent Application Serial No. 08/396,414, entitled APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure.

[REDACTED]

Therefore, there exists a need for spinal fusion implants and instrumentation that permits for the uniform depth of bone removal from each of the adjacent vertebrae while restoring anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially conical configuration and the instrumentation and methods by which the implants of the present invention can be utilized to achieve a desired anatomical lordosis of the spine.

The spinal fusion implants of the present invention may be partially or fully conical with truncated ends. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a cone, the side portions form straight walls. These implants may have a more tapered aspect at the small end of the cone to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid, may have surface roughenings to promote bone ingrowth and stability, may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation, these holes may pass, either into or through the implant. Said implants may have a hollow central chamber, which chamber may be in communication through various openings to the surface of the implant and which chamber may be capable of being closed off with a cap. Still further, a variety of surface irregularities may be

employed to increase the implant stability and surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings, threads or other surface irregularities sufficient for these purposes. The spinal fusion implant of the present invention may be made of a mesh-like material, porous material, or any metal, plastic, ceramic or combination sufficient for the intended purpose. Said implants may be composed of, or treated with materials to make them bioactive to the fusion process. Said implant may be wholly or in part bioabsorbable.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially conical and taper from the leading edge to the trailing edge, they are easy to introduce and easy to fully insert into the spinal segment to be fused.

2. As the spinal fusion implants of the present invention are generally implanted from the anterior to posterior aspect of the spine, the shape of the implants are consistent with the shape of the disc, which the implant at least in part replace. That is the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The present invention implants are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody fusion in lordosis.

4. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal

fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, the spinal fusion implants of the present invention may be comprised, wholly or in part, of materials capable of directly participating in the spinal fusion process, or coated with chemical substances such as bone morphogenic proteins for the purpose of stimulating fusion activity. Said implant may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is partially conical with a substantially even cylindrical external thread.

Figure 2 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body and an external thread that are both partially conical.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a partially conical body and a surface configuration comprising ratchetings for engaging bone, with surface blasting,

wells, and channels for bone ingrowth.

Figure 5 is a cross sectional view along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the implant of the present invention.

Figure 6 is a cross sectional view along line 6--6 of the implant of Figure 4 illustrating the channels and walls of the implant of the present invention.

Figure 7 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous metal mesh that is partially conical with one side that is truncated shown next to an identical second implant illustrated in hidden line.

Figure 8 is sectional view along line 8--8 of the implants of Figure 7.

Figure 9 is an enlarged fragmentary view along line 9 of Figure 7 illustrating the surface configuration of the implant of Figure 7.

Figure 10 is a side elevational view in partial cut-away of an alternative embodiment of the spinal fusion implant of the present invention having a body that is partially conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 11 is an enlarged fragmentary sectional view along lines 11--11 of Figure 10 illustrating the surface configuration of the implant of Figure 11.

Figure 12 is a front elevational view of a segment of the spinal column in lordosis having a first drill and a second drill for boring a hole across the disc space and into the adjacent vertebrae with the method of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is partially conical in shape such that the body 22 has a diameter (root diameter) that is partially conical. The body 22 has an

insertion end 24 and a trailing end 26. The implant 20 has an external thread 28 that is a substantially even cylinder, such that the external diameter of the threads (major diameter) has a substantially even cylindrical configuration. While the major diameter of the implant 20 is substantially cylindrical in shape, the external thread 28 may be modified at the leading edge by having initially a reduced thread height to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 may be modified at the leading edge by having initially a reduced thread height to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser height than the remainder of the external thread to facilitate insertion of the implant 20. The second thread 32 has a greater height than the first thread 30, but is still shorter than the remainder of the external thread 24.

The conical configuration of the body # allows for the creating and maintaining of the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The external thread 28 of the implant 20 are configured in a substantially cylindrical shape in order to engage the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the opposite direction in which the implant 20 was implanted.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to the insertion instrumentation.

The implant 20 has an outer surface 38 that is roughened such as by blasting in order to present an irregular surface to the bone to promote bone ingrowth. It is appreciated that the outer surface 38 may have any other surface irregularity to promote bone ingrowth, such as, but not limited to, knurling, ratchetings, openings, wells, channels or a fibrous mesh, described in detail

for the alternative embodiments set forth below. The implant 20 is shown as being solid, however it is appreciated that it can be made to be entirely hollow or hollow in part. In the preferred embodiment, the implant 20 has an overall length in the range of approximately ____mm to _____mm with _____mm being the preferred diameter range. In the preferred embodiment, the body 22 has a maximum diameter portion in the range of ____mm to _____mm with ____mm being the preferred maximum diameter. The body 22 has an overall partially conical configuration.

Referring to Figure 2, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 120. The implant 120 has a body 122 that is partially conical similar to body 220 of implant 20, and has an insertion end 124 and a trailing end 126. The implant 20 has an external thread 128 that parallels the body 122 such that the external thread 128 is also partially conical in shape. The implant 120 has an outer surface with large openings 140 and small openings 142 permitting bone ingrowth into the implant 120.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142 to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to one end of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber

146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 130 and/or the spinal fusion implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a partially conical body 222 that is similar to body 22 of implant 20 and has a surface configuration suitable for engaging the bone of the adjacent vertebrae.

The surface configuration of the implant 220 comprises surface roughenings suitable for engaging the adjacent vertebrae to stabilize the implant 220 across the disc space and into the adjacent vertebrae once surgically implanted. In one embodiment of the implant 220, the surface roughenings comprise a plurality of ratchetings 240 along the circumference of the implant 220. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and an angled segment 244.

Each of the plurality of ratchetings 240 have a height that is significantly less than the requisite height of a thread of a same sized threaded implant. The implant 220 is implanted across the disc space and into the adjacent vertebrae by linear advancement. As no torque is required to advance the implant 220 there is no minimum requisite height of the surface roughenings. The only surface feature necessary is that which gives the implant 220 stability once implanted.

Moreover, the ratchetings 240 may face in one direction, the direction in which the implant 220 is inserted, and function to

prevent the implant 220 from backing out of the disc space in a direction opposite to the direction of insertion once inserted between the two adjacent vertebrae. The ratchetings 240 urge the implant 220 forward against the unremoved bone of the vertebrae. Since implants generally want to back out along the same path in which they are inserted, such as repeated movement of the patient's body over time and which would cause some other design of implant to come loose (e.g. cause a threaded cylindrical implant to possibly unscrew), the ratchetings 240 tend to urge the implant 220 forward against the solid unremoved bone further resisting dislodgement and controlling motion resulting in an exceedingly stable implantation.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured from the root diameter of the implant 220 in the range of 0.25 - 1.5 mm, with the preferred height range being 0.35 - 0.75 mm.

Referring to Figures 5 and 6, a cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter in the range of 0.1 mm to 6 mm with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figures 7-9, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320a. The implant 320a is shown placed to a second implant 320b shown in hidden line. The implant 320a has a body 322 that is made out of fibrous metal strands that are pressed together and molded into a conical configuration. The implant 320a has an insertion end 324 and a

trailing end 326 and may be made entirely of fibrous metal strands or may comprise an outer covering made of the fibrous metal strands. It is appreciated that the implant 320a may be solid or may be partially hollow and include an internal chamber. As shown in Figure 9, the fibrous metal strands are formed and pressed together such that intersects 339 capable of receiving bone during bone ingrowth are wells # are present between the fibrous metal strands in the outer surface 338 of implant 320.

The implant 320a is partially conical, similar to implant 20, referring to Figure 8, the implant 320a has at least one truncated side 340 allowing for the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No. 08/390,131, incorporated herein by reference.

Referring to Figure 10, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body 422 that is partially conical in shape having an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding natural or artificial bone material and capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate fusion promoting substances.

Referring to Figure 11, an enlarged view of the surface 438 of implant 420 is shown. In the preferred embodiment, the posts 440 have a head portion 444 of a larger diameter than the remainder of the posts 440, and the each of the interstices 442 is the reverse configuration of the posts 444 having a bottom 446 that is wider than the entrance 448 to the interstices 442. Such a configuration of the posts 440 and interstices 442 aids in the

retention of bone material in the surface 438 of the implant 420 and further assists in the locking of the implant 420 into the bone fusion mass created from the bone ingrowth, while providing for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts 440 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 442 have a width in the range of approximately 0.1 to 2mm.

The embodiments of the conical implants of the present invention described above may be implanted with the method described below. In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis have been achieved at the affected disc level, then a conical space is created from anterior to posterior between the adjacent vertebrae. The space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae. The created space is generally conical in shape, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepared two such spaces side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the space is prepared and all debris removed, the implant is then inserted into the prepared

space across the disc space, penetrating into each of the adjacent vertebrae, from anterior to posterior.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. 08/396,414 incorporated herein by reference is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the cervical spine. As previously described in pending U.S. Patent Application Serial No. _____, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. _____, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described interspace distractor. However, if the interspace distractor is used thenafter the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

Referring to Figure 12, a segment of the spinal column S is shown with a first drill 510 having an opening 512 across the disc space D, and into adjacent vertebrae V1 and V2, and a second drill 520 having an opening 522 across the disc space D2 and into adjacent vertebrae V2 and V3. In the preferred embodiment, the interbody spinal fusion implant itself is a threaded cone and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention.

with the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root dimensions of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion of the first drill 510 corresponding to the conical shape of the root diameter of the implant being inserted. This instrument may take the form of a conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with power. At this time, the surgeon has two options: One is to remove the outer sleeve and then, because the implant is itself conical, screw the implant in using an implant driver capable of locking to the implant. [REDACTED]

The insertion of the implant causes a reproduction of the previous distraction which is easily achieved as the implant itself is conical and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the device is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from it. If the cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same level such that a pair of implants may be inserted side-by-side.

However, if the surgeon wishes to leave the outer sleeve in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the drilling means needs to basically correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be great enough to allow the passage of the major diameter of the implant. Nevertheless, it is

desirable to stabilize the previously described bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. That may be achieved in one of two ways. First, a reduction sleeve may be introduced, which sleeve fit between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant. Or secondly, some portion of the drill shaft proximal to the actual part engaged in the removal of bone may have a diameter which roughly corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In that way, the bone removal instrument is both stabilized and centered within the outer sleeve.

The basic described principles of the prior discussion are also applicable to the lumbar spine. The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No. 08/396,414 from which the present methods differ only in the shape of the drill end or bone milling device which is essentially conical. As also previously described, in that co-pending application Serial No. 08/396,414, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application 08/390,131, the implants themselves may have tangential truncations such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height.

In an alternative method of implant insertion, the use of at least partially conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is

present to begin with. As an example, a disc space which in the preferred circumstance would be fully distracted but need not be, but lacking lordosis, could have a bore drilled across that space such that equal arcs of bone are removed from each of the adjacent vertebrae using a drill or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The essential feature here is that the vertebrae, whether distracted from each other or not are essentially lacking the full restoration of lordosis. The use of the substantially cylindrical bone removal instrument, (e.g. a drill), provides for the removal of a generally uniform thickness of bone from each of the adjacent vertebrae from anterior to posterior. The insertion of a conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart more so than the posterior aspects where the diameter is lesser. This utilizes the implant to produce the desired lordosis.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

What is claimed is:

1. A partially conical spinal fusion implant made of a material appropriate for human implantation, comprising:

a partially conical body having an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae in a segment of the spinal column.

2. The spinal fusion implant of claim 1 in which said bone engaging means comprises an external thread.

3. The spinal fusion implant of claim 2 in which said external thread has a substantially cylindrical external configuration.

4. The spinal fusion implant of claim 2 in which said external thread has a partially conical configuration that parallels the configuration of said body.

5. The spinal fusion implant of claim 2 in which said bone engaging means comprises said body having a roughened outer surface chamber of receiving bone ingrowth.

6. The spinal fusion implant of claim 1 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

7. The spinal fusion implant of claim 7 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

8. The spinal fusion implant of claim 1 in which said bone engaging means comprises a fibrous material comprising a plurality of fibrous strands randomly spaced apart creating a plurality of interstices for receiving bone material.

9. The spinal fusion implant of claim 8 in which said fibrous

material is made of a surgically implantable metal.

10. The spinal fusion implant of claim 1 in which said implant has and internal chamber.

11. The spinal fusion implant of claim 10 in which said internal chamber is capable of containing fusion promoting material.

12. The spinal fusion implant of claim 10 in which said implant comprises a wall surrounding said internal chamber.

13. The spinal fusion implant of claim 12 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

14. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

15. The spinal fusion implant of claim 1 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of the outer surface of said implant.

16. The spinal fusion implant of claim 15 in which said surface roughenings include a plurality of ratchetings.

17. The spinal fusion implant of claim 11 in which said ratchetings face one direction.

18. The spinal fusion implant of claim 15 in which said surface roughenings include knurling.

19. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

20. The spinal fusion implant of claim 10 in which said implant has at least one removable cap for closing at least one end of said internal chamber.

21. The spinal fusion implant of claim 1 in which one end of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

22. A partially conical spinal fusion implant made of a material appropriate for human implantation, said spinal fusion implant comprising a partially conical body having a maximum diameter portion; said body having an exterior surface configured to be placed in close proximity to a second partially conical spinal fusion implant, said first and second implants when placed together having a combined overall width that is less that the sum of the individual maximum diameters of each of said first and second implants.

23. The spinal fusion implant of claim 22 having a longitudinal central axis and at least one flat side parallel to said central axis.

30. A method for inserting at least one partially conical spinal fusion implant made of a material appropriate for human implantation, said implant comprising a partially conical body and bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc and placing the two vertebrae in the desired amount of lordosis;

drilling a recipient bore across the disc space and into the adjacent vertebrae, said bore being greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a partially conical spinal fusion implant into said recipient bore.

31. The method of claim 30 in which said bore is generally conical in shape.

32. The method claim 31 in which said bore is greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

ABSTRACT

EXHIBIT D

LEWIS ANTEN
A PROFESSIONAL CORPORATION
16830 VENTURA BOULEVARD
SUITE 411
ENCINO, CALIFORNIA 91436
TELEPHONE (818) 501-3535
TELECOPIER (818) 501-3618

TELECOPY TRANSMISSION SHEET

CONFIRM RECEIPT: YES X NO____

DATE: April 20, 1995

TO: Ms. Eva Renkei Fax No.: (818) 766-9849

FROM: Amedeo Ferraro, Esq.

RE: Conical Spinal Fusion Implants
Our File No. P-12509

NO. OF PAGES (INCLUDES THIS COVER SHEET): 3

MESSAGE:

Thank you for the preliminary sketch of your drawings. Your disclaimer has been noted and accepted. With that in mind and in the interest of saving time, I have made some comments on the enclosed sheets to assist you in preparing the actual drawings.

Please call me if you have any questions.

IF YOU DO NOT RECEIVE A CLEAR OR COMPLETE FAX, PLEASE CALL US AT (818) 501-3535. OUR FAX NUMBER IS (818) 501-3618